

**IN THE UNITED STATES DISTRICT COURT  
FOR THE EASTERN DISTRICT OF PENNSYLVANIA**

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|--|---|-----------------------|
| <b>UNITED STATES OF AMERICA <i>ex rel.</i></b> | : | : <b>CIVIL ACTION</b> |
| <b>HERBERT J. NEVYAS, M.D., and</b>            | : |                       |
| <b>ANITA NEVYAS-WALLACE, M.D.</b>              | : |                       |
|  | : |                       |
| v.   | : |                       |
|  | : | : <b>NO. 09-432</b>   |
| <b>ALLERGAN, INC.</b>                          | : |                       |

**ORDER**

**AND NOW**, this 26th day of May 2015, upon consideration of Defendant's Amended Motion to Dismiss Relators' Second Amended Complaint ("SAC") and supporting memoranda (ECF Doc. Nos. 62, 68, 83, 97), Relators' Opposition and supporting memoranda (ECF Doc. Nos. 65, 67, 88, 98), United States' Statements of Interest (ECF Doc. Nos. 66, 87, 94), and following oral argument, it is **ORDERED** the Defendant's Amended Motion to Dismiss Relators' Second Amended Complaint is **GRANTED in part and DENIED in part**.

1. Defendant's motion under Fed.R.Civ.P. 12(b)(6) and 9(b) to dismiss Count I alleging a violation of the False Claims Act, 31 U.S.C. §3729 *et seq.* ("FCA") is **DENIED**.<sup>1</sup>

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<sup>1</sup> In enacting the FCA, "Congress wrote expansively, meaning 'to reach all types of fraud, without qualification, that might result in financial loss to the Government.'" *Cook Cnty., Ill. v. U.S. ex rel. Chandler*, 538 U.S. 119, 129 (2003) (quoting *United States v. Neifert-White Co.*, 390 U.S. 228, 232 (1968)). "The primary purpose of the FCA 'is to indemnify the government - through its restitutionary penalty provisions - against losses caused by a defendant's fraud.'" *U.S. ex rel. Wilkins v. United Health Gr., Inc.*, 659 F.3d 295, 304 (3d Cir. 2011) ("*Wilkins*") (quoting *Mikes v. Straus*, 247 F.3d 687, 696 (2d Cir. 2001)). We address Defendant's multiple challenges to Count I *seriatim*.

**False Claims Act ("FCA"):** Relators state a claim under the FCA. An FCA *prima facie* claim requires plaintiff plead "(1) the defendant presented or caused to be presented to an agent of the United States a claim for payment; (2) the claim was false or fraudulent; and (3) the defendant knew the claim was false or fraudulent." *Wilkins*, 659 F.3d at 311-12 (quoting *U.S. ex rel. Schmidt v. Zimmer, Inc.*, 386 F.3d 235, 242 (3d Cir. 2004) ("*Schmidt*"). Compliance with the Anti-Kickback Statute, 42 U.S.C. §1320a-7b ("AKS") is a material condition of payment under federal health programs such as Medicare, and false certification of compliance is actionable under the FCA. *Wilkins*, 659 F.3d at 312-13. Relators sufficiently allege (1) Allergan "caused to be presented" to the United States (2) claims tainted by

Allergan's alleged scheme to induce physicians to write prescriptions for Allergan products by providing those physicians remuneration in violation of the AKS rendering such claims "false or fraudulent;" which (3) Allergan knew to be "false or fraudulent." We do not read *Wilkins* to foreclose FCA claims - and effectively immunize from FCA liability pharmaceutical companies who rely on unknowing pharmacists to seek reimbursement - where Allergan allegedly caused false claims to be submitted to the United States rather than physicians or Allergan itself. We do not find *Wilkins* to be incompatible with *U.S. ex rel. Hutcheson v. Blackstone Med., Inc.*, 647 F.3d 377 (1<sup>st</sup> Cir. 2011). Relators state an FCA claim within the holding of *Schmidt* - cited and relied upon by the court in *Wilkins* - and recent decisions from courts within this District allowing such claims to proceed at the motion to dismiss stage. See *U.S. ex rel. Boise v. Cephalon, Inc.*, No. 08-287, 2015 WL 1724572 (E.D. Pa. Apr. 15, 2015); *U.S. ex rel. Bates v. Dentsply International, Inc.*, No. 12-7199, 2014 WL 4384503 (E.D. Pa. Sept. 4, 2014); *U.S. ex rel. Bergman v. Abbott Labs.*, 995 F.Supp. 2d 357 (E.D. Pa. Jan. 30, 2014). We find persuasive *U.S. ex rel. Cairns v. D.S. Medical LLC*, No. 12-4, 2015 WL 590325 (E.D. Mo., Feb. 11, 2015) as well as *U.S. ex rel. Brown v. Celgene Corp.*, No. 10-3165, 2014 WL 3605896 (C.D. Ca. July 10, 2014). In *Cairns*, the district court citing both *Hutcheson* and *Wilkins* rejected the argument Allergan advances here holding "a non-submitting party may be liable for causing the submission of such a false claim by another party, and that this liability is not conditioned on whether the submitting party knew about the non-submitting party's unlawful conduct." *Cairns*, 2015 WL 590325 at \*5. In *Brown*, the district court, citing *Bergman*, found "even though [defendant] did not itself falsely certify compliance with any legal condition of payment, it is still susceptible to liability because it allegedly caused claimants to implicitly make such false certifications and thereby caused the submission of false claims." *Brown*, 2014 WL 3605896 at \*3.

**FCA claim/scienter:** Relators sufficiently allege scienter. The FCA defines "knowing" and "knowingly" as including a defendant's "actual knowledge," "deliberate ignorance," or "reckless disregard" of the "truth or falsity of the information" of the claims. 31 U.S.C. §3729(b)(1)(B). Relators allege Allergan knowingly and willfully offered illegal kickbacks to eye care professionals to induce them to prescribe Allergan products (SAC at ¶¶ 203, 305-309, 310-319). Relators further allege Allergan knew or should have known that pharmacists and physicians would file false and fraudulent claims with the federal and state governments for payment on the claims tainted by kickbacks (*Id.*). Consistent with *Schmidt*, and reading the SAC in the light most favorable to Relators, we reasonably read the allegation as Allergan knew that prescriptions written by physicians induced by kickbacks would be submitted to the United States for payment through pharmacists. See *Schmidt*, 386 F.3d at 244.

**FCA claim/causation:** Relators sufficiently allege Allergan's scheme caused a financial loss to the United States. See *Schmidt*, 386 F.3d at 244-45. Relators are not required to "allege that falsity caused an actual loss to the government." *U.S. ex rel. Simpson v. Bayer Corp.*, No. 05-3895, 2013 WL 4710587, \*14 (D.N.J. Aug. 30, 2013). In *Simpson*, the complaint sufficiently alleged causation where the defendant's "illegal kickback scheme engineered to induce medical providers to prescribe [defendant's drugs] . . . would inevitably cause false claims to be submitted to the government by healthcare providers." *Id.* (citing *Schmidt*, at 243-244). Here, Relators allege the scheme to induce physicians to prescribe Allergan products; Allergan knew that its illegal kickback scheme would increase the prescription of its products; Allergan knew or should have known that pharmacists and physicians would necessarily submit false claims with the government when seeking reimbursement for Allergan products; Allergan's illegal kickback scheme caused the submission of false or fraudulent claims to federal and state healthcare programs; and each prescription and claim arising out of Allergan's scheme are a result of a kickback, are false, and violate the FCA and analogous state statutes (SAC at ¶¶305-319). These allegations are sufficient to plead causation. See *Bergman*, 995 F.Supp. 2d at 374-75 ("when a relator

alleges a kickback scheme large enough such that the submission of false claims is inevitable, then the relator has sufficiently alleged causation under 9(b)).

**AKS claim:** Relators sufficiently plead an AKS violation, showing Allergan “(1) knowingly and willfully (2) solicited or received remuneration (3) in return for, or to induce, referrals to a person or entity for services covered by Medicare, Medicaid, or any other federally funded healthcare program.” *U.S. ex rel. Bartlett v. Ashcroft*, 39 F. Supp. 3d 656, 676 (W.D. Pa. 2014). “The statute has been broadly interpreted to cover any arrangement where *one purpose* of the remuneration is to obtain money for the referral of services or to induce future referrals.” *Id.* (citing *United States v. Greber*, 760 F.2d 68, 72 (3d Cir.1985)) (emphasis in original). Relators allege Allergan knowingly engaged in a scheme to provide financial remuneration to physicians and optometrists inducing them to prescribe and recommend Allergan products and the prescribing physicians and optometrists then directed referrals of patients in federally-funded healthcare programs to Allergan’s products in violation of the AKS and analogous state laws (SAC at ¶¶ 305-309).

**AKS claim/remuneration:** Relators sufficiently allege additional inducements in the form of speaker fees, an Allergan-paid trip to Manhattan with consultant fee and travel stipend, and an offer to fund independent research to reward top prescribers constituting “remuneration” within the meaning of the statute (SAC at ¶¶286-291; ¶¶292-302; ¶¶303-304); 42 U.S.C. §1320a-7a(i)(6) (“items or services for free or for other than fair market value”).

**AKS claim/First Amendment defense:** Allergan’s reliance on *Sorrell v. IMS Health Inc.*, \_\_\_ U.S. \_\_\_, 131 S.Ct. 2653, 180 L.Ed 2d 544 (2011) in support of its First Amendment defense to the AKS claim is unavailing. Accepting as true the SAC’s allegations at this preliminary stage, Relators allege a scheme by Allergan to induce physicians to write prescriptions for Allergan products in violation of the AKS; it is Allergan’s *conduct* in providing “illegal remuneration” to physicians and optometrists and not its speech that is at issue in the AKS claim. *See* AKS, 42 U.S.C. §1320a-7b(b). Allergan does not cite any court invalidating the AKS on the basis of a First Amendment violation. *See Bergman*, 995 F.Supp. 2d at 375-76; *see also U.S. v. Mathur*, No. 11-312, 2012 WL 4742833, \*8-\*10 (D. NV. Sept. 13, 2012).

**Rule 9(b):** The SAC meets the pleading requirements of Rule 9(b) under *Foglia v. Renal Ventures Mngmt, LLC*, 754 F.3d 153 (3d Cir. 2014). In *Foglia*, our Court of Appeals adopted a “nuanced” approach to the heightened pleading requirements of Rule 9(b), holding a claimant must provide “particular details of a scheme to submit false claims paired with reliable indicia that lead to a strong inference that the claims were actually submitted.” *Foglia*, 754 F.3d at 157-58 (quoting *U.S. ex rel. Grubbs v. Kanneganti*, 565 F.3d 180, 190 (5th Cir. 2009)). Relators meet the *Foglia* standard.

**Rule 9(b)/nationwide scheme:** We deny Allergan’s motion to dismiss Relators’ claims related to Medicaid programs under FCA-analogous state (and District of Columbia) statutes. Under the *Foglia* standard, Relators sufficiently allege Allergan’s nationwide scheme violating the AKS to induce approximately 1,500 physicians across the United States to write prescriptions for Allergan products by enrolling them in the “special program” providing business advisory services on the *Allergan Access* website (SAC at ¶¶105, 110, 118, 218). Although Relators do not specifically plead actions in each state, Allergan does not presently argue Relators fail to plead the elements of a claim under any state statute.



2. Defendant's Motion to Dismiss Count XIV under the New Mexico Medicaid False Claims Act is **GRANTED**.<sup>2</sup> Count XIV is dismissed in its entirety.

3. Defendant's Amended Motion to Dismiss Count XV under New York's False Claims Act based on a retroactive application of state law argument is **DENIED**.<sup>3</sup>

4. Defendant's motion to limit damages recoverable under Counts I, III, IV, V, VI, VII, VIII, IX, X, XI, XII, XIII, XV, XVI, XVII, XVIII, XIX, and XXI based solely on statutes of limitations, state non-intervention, and retroactive application of state law is **GRANTED**<sup>4</sup> **such that** Relators' damages, if any, for these Counts are limited to the dates identified on Relators' chart at pages 74-75 of Relators' Response to Allergan's Amended Motion to Dismiss, with the exception of Count XIX under the Virginia Fraud Against Taxpayers Act<sup>5</sup> which is limited to claims submitted on or after November 12, 2003 (ECF Doc. No. 65). All other grounds for Defendant's motion to dismiss Counts I through XIII and XV through XXI are **DENIED**.

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<sup>2</sup> Relators agreed to voluntarily dismiss their claim under the New Mexico Medicaid False Claims Act, N.M. Stat. Ann. §27-14-4A, C (West 2015). See Relators' Response to Allergan's Amended Motion to Dismiss at 75 (ECF Doc. No. 65).

<sup>3</sup> New York's False Claims Act, N.Y. State Fin. §187 *et seq.* (McKinney 2007) applies retroactively. See *U.S. ex rel. Bilotta v. Novartis Pharm. Corp.*, 50 F. Supp. 3d 497, 540-41 (S.D.N.Y. 2014); *U.S. ex rel. Boise v. Cephalon, Inc.*, No. 08-287, 2015 WL 1724572, \*15 (E.D. Pa. Apr. 15, 2015).

<sup>4</sup> While Allergan seeks to dismiss or limit Counts I through XIII and XV through XXI based on statutes of limitations, state non-intervention, and/or retroactivity grounds, we cannot find any argument to dismiss claims under California's False Claims Act, Cal. Gov't Code §12651 (West 2015) (Count II) or Wisconsin's False Claims Act, Wis. Stat. Ann. §20.931 (West 2015) (Count XX), and neither California nor Wisconsin are contained on the chart submitted by Allergan in its moving brief at pages 35-36 (ECF Doc. No. 62-1). Accordingly, those claims remain as defined by Relators' chart at pages 74-75 of their Response (ECF Doc. No. 65).

<sup>5</sup> There is a 6-year statute of limitations for actions under Virginia's Fraud Against Taxpayers Act, Va. Code Ann. §8.01-216.1; §8-01-216.9. Relators' damages under the Virginia statute are limited to claims submitted on or after November 12, 2003, the date of Relators' First Amended Complaint.

5. Defendant shall answer the Second Amended Complaint on or before June 25, 2015.



KEARNEY, J.